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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., AND NORTON (WATERFORD) LTD., PLAINTIFFS, V. CIPLA LTD, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC, DEFENDANTS	Consolidated Civil Action No. 2:20-CV-10172-MCA-MAH

DEFENDANTS' OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

The patents-in-suit[1] are directed to narrow alleged inventions in the crowded field of dose counters for drug inhaler devices. In an attempt to avoid the extensive prior art in the field, Plaintiffs developed a very particular dose counter—one using tape to display remaining doses. The asserted claims are generally directed to this particular method of counting doses. Despite Defendants' devices undisputedly lacking any tape, Plaintiffs nevertheless asserted ***seven*** patents against Defendants. Although Plaintiffs belatedly dropped two of the most egregiously asserted patents, notably only ***after*** Defendants were forced to prepare extensive invalidity contentions covering over 70 asserted claims, Plaintiffs ***still*** assert 42 clearly non-infringed claims across the five remaining patents. In the Joint Claim Construction Chart, Plaintiffs acknowledged their intent to drop additional claims, making "it unnecessary to construe at least some of the claim terms presently proposed for construction." Yet, Plaintiffs continue to refuse to reduce the number of improperly asserted claims at this time, again forcing Defendants (and the Court) to engage in extensive work construing claim terms Plaintiffs appear to already know will not be at issue at trial.

In an attempt to delay generic competition, Plaintiffs seek to use claim construction to broaden the reach of their claims well beyond the narrow scope granted by the Patent Office. Plaintiffs' proposed constructions ignore the specific disclosures in the specification, ignore the arguments made to the Patent Office in support of patentability, and ignore common sense. Indeed, Plaintiffs' overbroad constructions would read on the prior art. Plaintiffs' litigation-driven constructions, written solely in an attempt to capture Defendants' non-infringing products, should be rejected.

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[1] U.S. Patent Nos. 9,463,289 ("the '289 Patent"); 9,808,587 ("the '587 Patent"); 10,086,156 ("the '156 Patent"); 10,561,808 ("the '808 Patent"); and 10,695,512 ("the '512 Patent"), attached to the declaration of Karen M. Cassidy as Exhibits 1-5, respectively. Because all of the patents-in-suit share a common specification, Defendants cite the '289 Patent specification.

Defendants' constructions, on the other hand, are consistent with the narrow disclosures in the specification, the narrow scope argued for by the Applicants during prosecution, and the narrow scope allowed by the Examiner. For all the reasons set forth herein, Defendants' proposed constructions should be adopted.

II. SUMMARY OF THE TECHNOLOGY

Each of the five remaining Asserted Patents share a common specification and all relate to an inhaler, and more specifically, the dose counter of the inhaler. None of the five Asserted Patents claim the drug or drug formulation. *See, generally*, Exs. 1-5. The inhaler described in the Asserted Patents is depicted below with the location of the dose counter noted for reference: ('289 Patent (Ex. 1) at Figs. 1 & 3B).

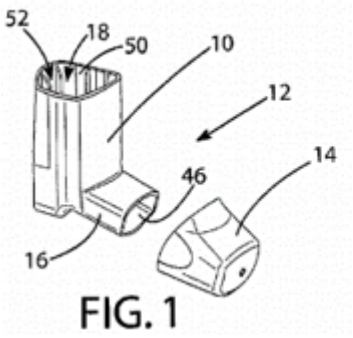


FIG. 1

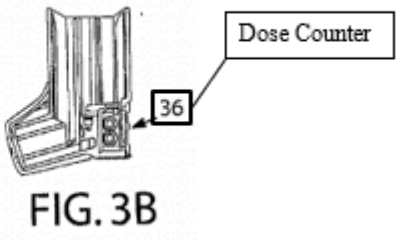
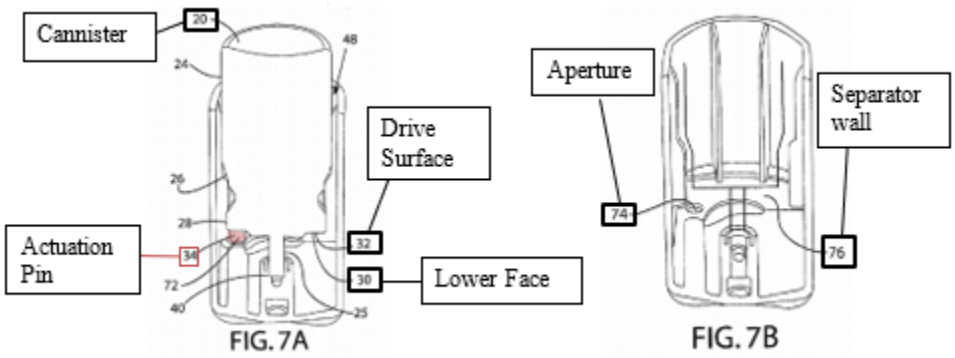


FIG. 3B

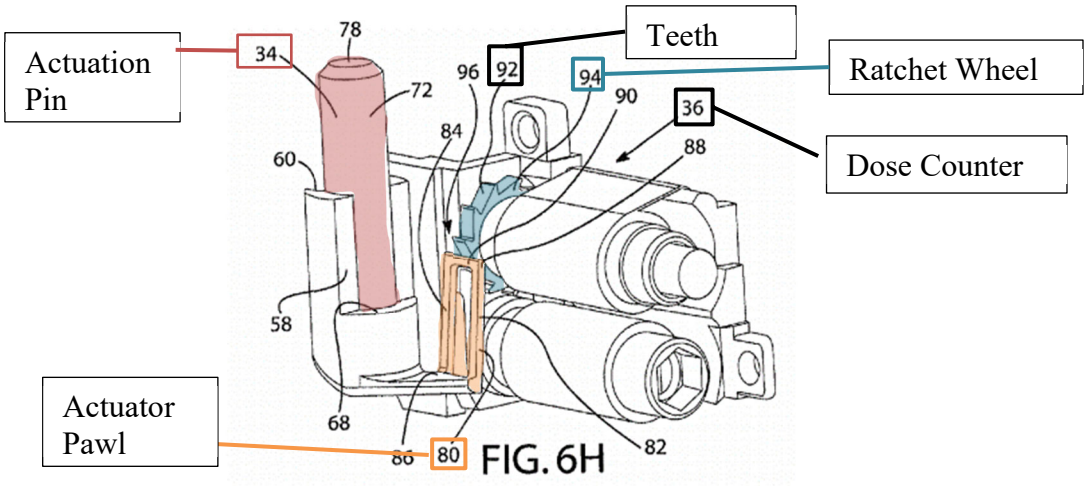
The inhaler and dose counter of the Asserted Patents contain a number of components, which the various Asserted Patents claim.

A. '289 and '587 Patents

When the claimed inhaler is used, a canister (containing a drug formulation) is placed into the main body of the inhaler and mates with a central outlet port. '289 Patent (Ex. 1) at 12:16-19. The canister is generally cylindrical and includes a lower face 30 which has an outer annular drive surface 32 that engages upon and drives an actuation pin 34 of the dose counter 36. *Id.* at 12:19-23. The actuation pin protrudes through an aperture 74 of the separator wall 76 of the main body 10 of the inhaler. *Id.* at 12:46-53. These features are depicted in Figures 7A and 7B, below:



The actuation pin 34 is biased upwardly by a spring. *Id.* at 12:39-41. The actuator pin is connected to an actuator pawl 80. *Id.* at 12:54-55. The actuator pawl is connected to the drive teeth 92 of the ratchet wheel 94 of the drive system of the dose counter. *Id.* at 12:55-13:2. These features are shown, for example, in Figure 6H, below:



When the user presses down on the canister with sufficient force, the canister depresses the actuator pin 34, causing the actuator pawl to rotate the drive teeth 92 of the ratchet wheel 94, and thereby causing the dose counter to count one dose (as describe in more mechanical detail below). *See id.* at 14:40-15:32. This movement is key to the claims of the '289 and '587 Patents, which are generally directed to an inhaler where the components are particularly arranged to avoid unintended movement of the actuation member.

The '289 and '587 Patents explain that the inhaler body includes a canister support formation that "can prevent a canister from rocking too much relative to the main body of the inhaler. Since the canister may operate the actuation member of the dose counter, this substantially improves dose counting and avoids counter errors." '289 Patent (Ex. 1) at 6:44-49. During prosecution, the Applicants explained that the particularly claimed arrangement of the actuation member, the central outlet port, and the inner wall canister support formation "has the advantage of preventing the canister from rocking towards the position of the dose counter actuation member, which rocking can change the height of the actuation member and thereby undesirably alter the accuracy of the dose counter." '289 Patent Prosecution History, March 7, 2016 Office Action Response (Ex. 6) at 5. In allowing the claims, the Examiner explained, "The examiner is persuaded that rocking by the canister about its central axis in the direction of the actuation member could risk triggering false counting, and that a canister support formation directly in line with the actuation member and the central canister axis could prevent rocking in this direction and thus reduce false counts." '289 Patent Prosecution History, May 20, 2016 Notice of Allowance (Ex. 7) at 2-3.

The '289 and '587 Patent claims are directed to a solution (a particular arrangement of canister support formations) to a particular problem (rocking of the canister that moves the actuation member causing unwanted dose counting). This solution is not the only method of avoiding the problem of unwanted dose counting by rocking "in the direction of the actuation member." For example, WO 2007/124406, discloses a system wherein, when the canister is depressed, it transfers movement to a pronged "indexer," (blue) and movement of the entire "indexer" causes a dose count to record. *See* '406 Publication (Ex. 8) at ¶ [00150].

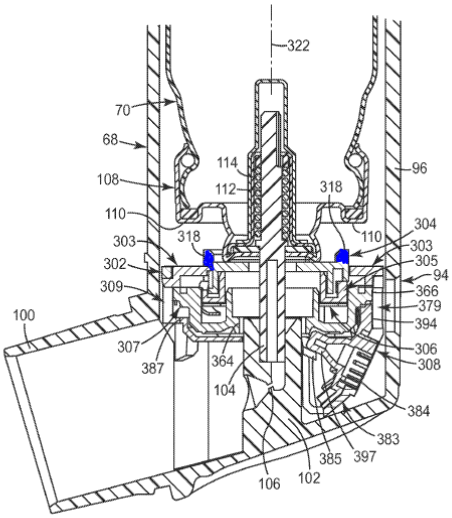


FIG. 27

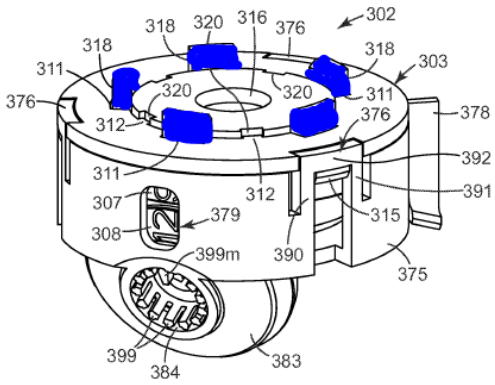


FIG. 24

Because the entire "indexer" moves to cause a count, rocking in the direction of only one prong, does not cause unwanted counting, as observed in systems like that claimed in the '289 and '587, where the "actuation member" is a single pin. The claimed invention is directed to a particular solution to a particular problem, not present in all inhalers, and as such the constructions should reflect this narrow invention.

B. <u>'156 Patent</u>

The claims of the '156 Patent are directed to a dose counter with an actuator pawl that is arranged to achieve certain positions during firing of the inhaler. *See, e.g.,* '156 Patent (Ex. 3) at claim 1. These positions include a first reset position, a canister fire configuration, and a count configuration. Citing Figures 10B-E, the specification describes the canister fire sequence, including the configurations making up the sequence in extensive detail.

The patent discloses that the canister fire sequence begins with a "start position" in which the canister has not yet been pressed down to engage the actuation member. *See* '289 Patent (Ex. 1) at 14:11-15. In this position, the count pawl engages the non-return back of a tooth of the ratchet wheel, while the actuator pawl has not yet engaged with a tooth of the ratchet wheel. *See* Figs.

10B (showing actuator pawl 98 spaced from the tooth (red circle) and count pawl 138 engaged with a different tooth (green circle)); 14:16-18, 14:47.

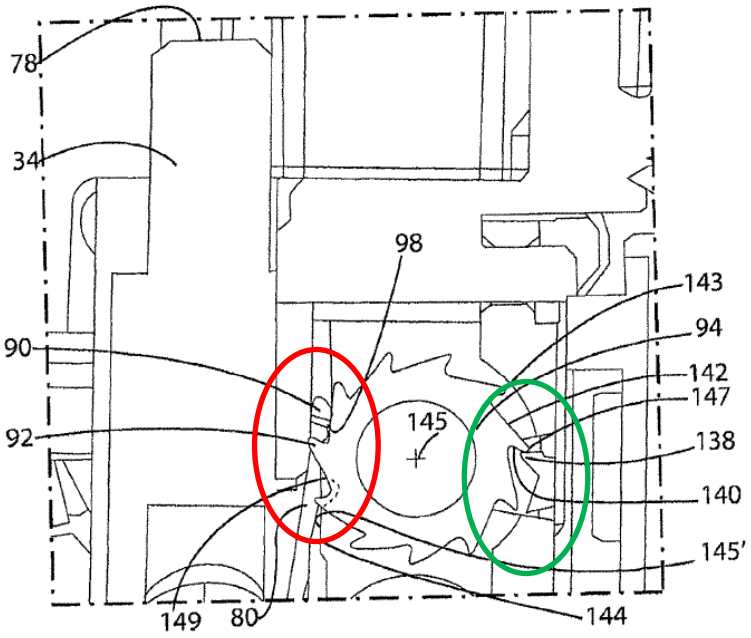


FIG. 10B

As the canister depresses the actuation pin, the actuator pawl depresses until it is "just engaged" with one of the teeth of the ratchet wheel—a position the patent identifies as the "reset position." *Id*. at Fig. 10C (showing actuator pawl 98 "just engaged" with tooth (red circle)), 14:42-49.

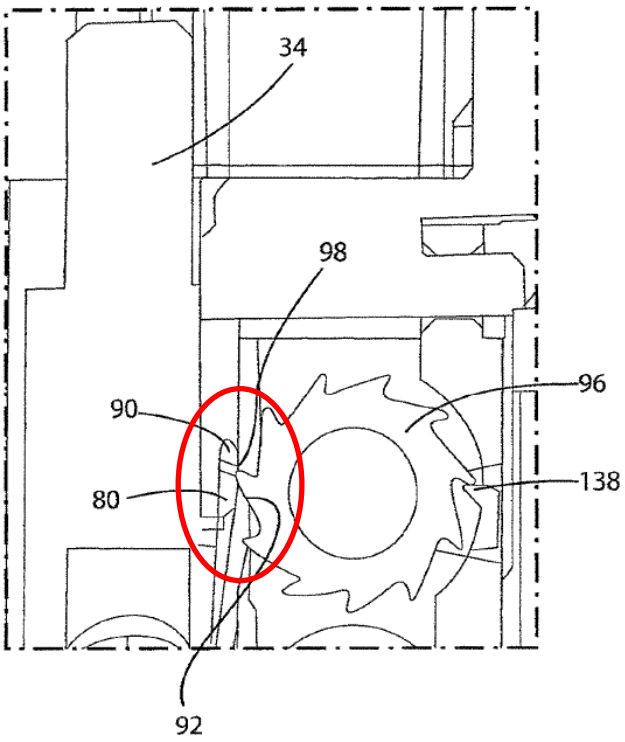


FIG. 10C

As the actuation member is further depressed, the actuation pawl lowers and rotates the ratchet wheel until the inhaler fires and ejects propellant. *Id.* at 14:50-61. At the point, the propellant is ejected, the device is in the "fire configuration," and the actuator pawl is below the datum plane line. *Id.*, Fig. 10D (showing the actuator pawl further depressed (red circle)).

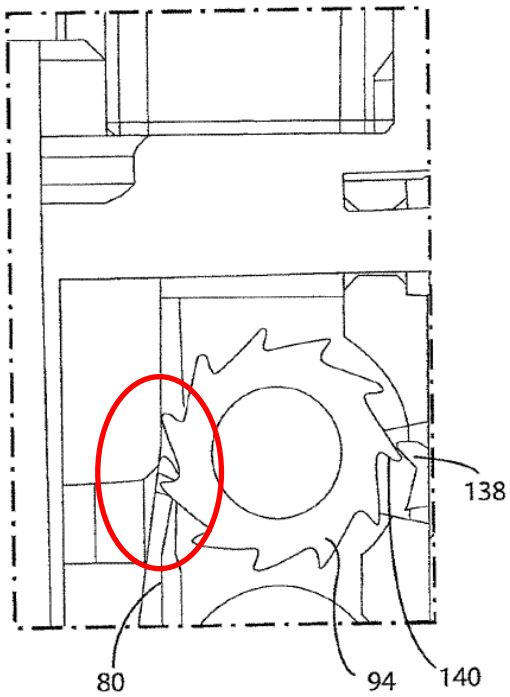
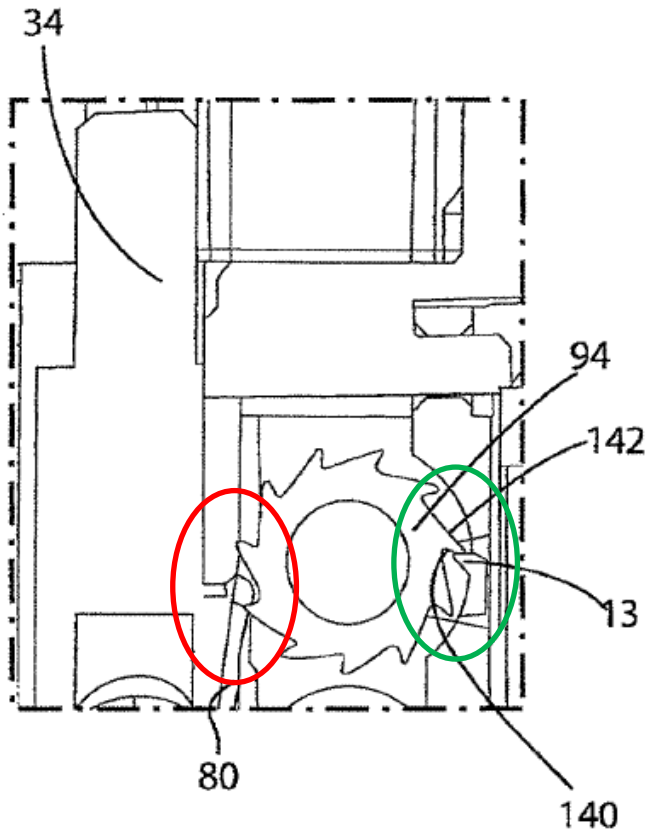


FIG. 10D

The datum plane is a required limitation of the patent claims, as the amendment requiring that the actuator pawl be below a datum plane passing through a shoulder of a valve stem block configured to receive the medicament canister, was the basis on which the claims were finally allowed after three years of prosecution. *See* '156 Patent Prosecution History, May 31, 2018 Notice of Allowance (Ex. 9) at 2. For this reason, identifying the datum plane is a necessary first step in evaluating the claims of the '156 Patent.

The patent next explains that the actuation pin is further depressed, causing the actuator pawl to rotate the ratchet wheel sufficiently that the count pawl jumps over the tooth of the ratchet wheel and is brought into engagement with the back surface of the next tooth. '289 Patent (Ex. 1) at Fig. 10E (showing the actuator pawl further depressed (red circle) and the count pawl engaged

with the back surface of the next tooth (green circle)) 14:62-15:14. At this point, the dose counter registers a count. *Id*.



C. ’808 Patent

The claims of the ’808 Patent are directed to movement of the counter display component of the dose counter. The counter display is the component of the inhaler that displays the number of doses remaining. For safety reasons, a user needs to know precisely how many doses remain without any ambiguity. The ’808 Patent describes a system wherein the counter display component is a tape moved from a first station, comprising a tape stock bobbin, to a second station comprising a tape reel shaft. ’289 Patent (Ex. 1) at 13:3-22. The ’808 Patent describes regulating movement of the counter display component through the interaction of a ribbed inner channel of

the stock bobbin 110 and a split pin shaft 108 positioned within the inner channel of the stock bobbin. *Id*. at 19:1-20:14. The interaction between the inner channel and the split pin is designed so that a level of force of an inhaler actuation causes compression of the split pin and the incremental movement of the stock bobbin relative to the split pin. *Id*. The force of the inhaler actuation rotates the tape reel shaft 106 around a shaft 104. *Id*. at 13:3-22, 19:1-20:14. Because the tape is fixed to the tape reel shaft 106, rotating the shaft will create tension in the tape and, upon overcoming the compression force in the split pin, a portion of the tape will move from the stock bobbin 110 to the tape reel shaft 106. *Id*. at 13:3-22, 19:1-20:14. This movement of the counter display (tape) from the first station (tape stock bobbin/shaft) to the second station (tape reel shaft) causes a new number to appear in the window 118 telling the user how many doses remain. *Id*. at 13:3-22.

D. ’512 Patent

The claims of the ’512 Patent are directed to avoiding unintended dose counting by firmly mounting the dose counter to the inhaler body through a process known as heat staking. *See* ’289 Patent (Ex. 1) at 7:65-66. The patent explains that heat staking the dose counter in place “further improv[es] counting accuracy compared to prior art arrangements in which some movement of the chassis relative to the bay may be tolerated in snap-fit connections.” *Id*. at 8:1-4.

The chassis is heat staked to the body of the inhaler by mating pins and apertures on “different sides” of the chassis. *See* ’512 Patent at claim 1. The language requiring “different sides” was first added during prosecution of a family member patent. During prosecution, the Applicants distinguished prior art that had multiple pins and apertures heat staked together on a single face of the inhaler body, from their invention having pins and apertures on “different sides.” *See* U.S. Patent 9,533,111, Prosecution History, Sept. 28, 2016 Office Action Response (Ex. 10) at 4. In distinguishing the prior art, the Applicant explained that having either the pins or apertures

on different sides of the chassis is beneficial because "such a feature is advantageous for firmly mounting the dose counter into the inhaler body." *Id.*

The '512 Patent further claims a dose counter chamber formed in the body. The patent repeatedly illustrates a chamber formed by separator wall 76 (e.g., the inner wall through which a portion of the actuation member extends) and the walls of the inhaler body (e.g., defined by the main surface of the inner walls), as shown, for example, in Figures 7C and 12 (separator wall shown in blue, inner walls shown in green).

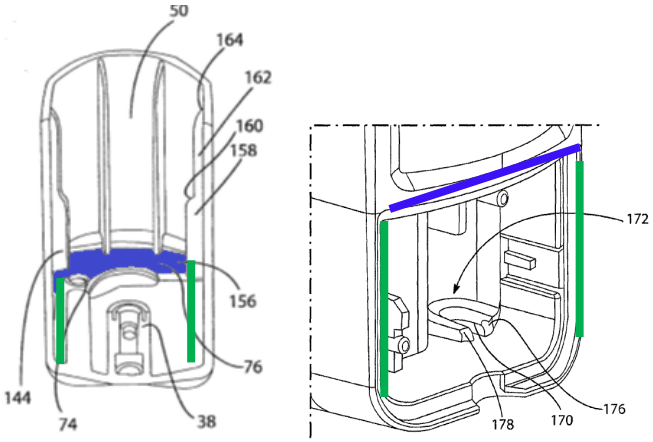


FIG. 12

III. ANALYSIS OF CLAIM TERMS IN DISPUTE

A. "actuation member"

Term	Defendants' Proposal	Plaintiffs' Proposal
"actuation member"	"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"	"a component of the dose counter's actuator that transmits motion from the canister to the actuator"

The Parties' dispute turns on two primary issues: (1) whether the construction should recite the purpose of the movement of the "actuation member" – that is engaging with the canister to effect movement that results in the dose counter recording a count, or merely any movement of the actuation member, and (2) whether the "actuation member" is a "pin," or more broadly any "component." Defendants' construction most accurately captures the structure disclosed in the specification and the purpose of the "actuation member" in view of the intrinsic record.

With respect to the function, it is undisputed that the "actuation member" must affect movement (or transmit motion) from the canister to the actuator, and Defendants' construction clarifies that such motion must cause the dose counter to record a count. That the movement effected or transmitted by the "actuation member" must cause a dose count is apparent from the specification, arguments made during prosecution, and the Examiner's reasons for allowance.

The Applicant's arguments during prosecution demonstrate that it is not just mere transmission of motion that matters, but how much motion is transmitted. Movement of the "actuation member" must be enough to cause a dose count to record a count. The Applicants argued that the support formations in the canister housing, the "actuation member," and the central outlet port are arranged in a particular configuration to prevent canister rocking "towards the position of the dose counter actuation member, ***which rocking can change the height of the actuation member and thereby undesirably alter the accuracy of the dose counter***." '289 Patent Prosecution History, March 7, 2016 Office Action Response (Ex. 6) at 5 (emphasis added). In short, Applicants argued that changing the height of the actuation member ***alone*** impacts accuracy of the dose counter. This can only be true if the actuation member is engaged with the canister and effects ***movement causing the dose counter to record a count.***

If, as in Plaintiffs' construction, the "actuation member" is merely a "component" or subset of a larger structure, such that the "component" alone is not required to transmit motion sufficient to cause a dose count, Applicant's arguments in the prosecution history are meaningless. Moreover, this rocking argument was the alleged novel premise on which the Examiner granted the patent. *See* '289 Patent Prosecution History, May 20, 2016 Notice of Allowance (Ex. 7) at 2-3 ("The examiner is persuaded that rocking by the canister about its central axis in the direction of

the actuation member could risk triggering false counting"). Plaintiffs' proposed construction, which renders the alleged point of novelty irrelevant, cannot be correct.

The specification also supports Defendants' proposed construction, repeatedly explaining that it is sufficient movement of the "actuation member" that ultimately causes a dose count to occur. *See* '289 Patent (Ex. 1) at 14:67-15:3 ("in this 'Count' configuration a sufficiently long stroke movement of the pin **34** has occurred that . . . the dose counter **36** will have just counted down one dose.") and 15:47-52 ("prevents the canister from wobbling and changing the height of the actuation pin **34** as to undesirably alter the accuracy of the dose counter **36**."). Thus, any construction must be clear that the "actuation member" itself is responsible for transmitting motion to cause a dose count.

The patent expressly defines the "actuation member" as a pin. *See* '289 Patent (Ex. 1) at 7:22-23 ("the actuation member comprising a pin extending through an aperture."). In addition, where the specification consistently uses words interchangeably, the interchangeable use of the terms "is akin to a definition equating the two." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009). The patent, and the Applicants during prosecution, repeatedly identify the "actuation member" as a "pin" and use the phrases "actuation member" and "actuation pin" interchangeably. *See* '289 Patent, Prosecution History, March 7, 2016 Office Action Response (Ex. 6) at 5 ("the actuation member at **74**"); '289 Patent (Ex. 1) at 12:47-49 ("The pin **34** . . . extends through an aperture **74**"), 12:38-39 ("[t]he dose counter **36** includes an actuation pin **34**"); *see also id.* at 12:50-53, 13:44-45, 14:7-8, 14:10-12, 14:40-42, 14:67-15:3, 15:47-52, 16:9-13. Figures 7A and 7B show the actuation pin (34) (red circle) and the aperture (74) through which the pin extends (green circle).

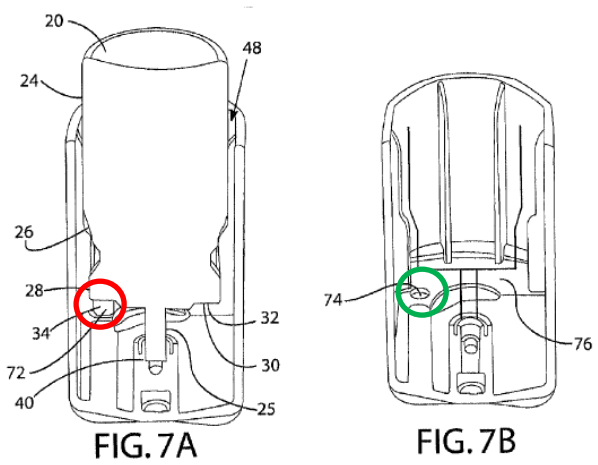


FIG. 7A FIG. 7B

Thus, it is clear from the intrinsic record that the "actuation member" is a "pin." Indeed, there is no other structure disclosed in the patents-in-suit that could possibly constitute an "actuation member," further supporting Defendants' construction.

By requiring that the "actuation member" is a pin that effects movement that causes a dose count, Defendants' construction remains consistent with the intrinsic record. Thus, Defendants' proposed construction should be adopted.

B. <u>"[lying or lie] in a common plane coincident with the longitudinal axis X"</u>

Term	Defendant's Proposal	Plaintiffs' Proposal
"[lying or lie] in a common plane coincident with the longitudinal axis X"	"aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member"	Features lie on a common plain coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block"

The Parties agree that this phrase requires a straight line to be drawn through the center of the central outlet port, a canister support formation, and the actuation member. The sole dispute is whether the canister support formation in the configuration must be located directly adjacent to the actuation member. Defendants' proposed construction should be adopted because it is consistent with the specification, the Applicants' arguments in support of patentability, and the Examiner's reasons for allowance.

During prosecution, the Applicants highlighted the particularly claimed arrangement of the actuation member, canister support formation, and central outlet port as an allegedly novel feature:

> By way of background to the instant invention recited in amended claim 1, the dash-dot line shown depicts how the inner wall canister support formation 144[(circled in purple), the actuation member at 74 [(circled in red)], and the central outlet port 148 [(circled in green)] lie in a common plane coincident with the longitudinal axis X at 148.

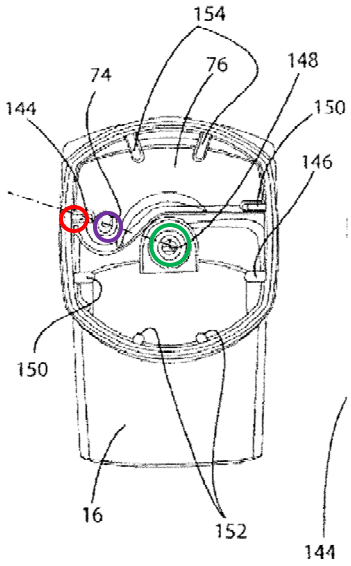


FIG. 7D

> . . . [T]he claimed arrangement has the advantage of ***preventing the canister from rocking towards the position of the dose counter actuation member***, which rocking can change the height of the actuation member and thereby undesirably alter the accuracy of the dose counter. . . .
>
> Applicant has discovered that by minimizing and/or eliminating the described rocking of the canister ***in the direction of the actuation member***, by way of the ***specific positioning of a canister support formation relative to the actuator*** and outlet port, the present invention improves accuracy of such dose counters. Neither the problem of canister rocking, nor the solution of ***specific placement of the canister support formation*** are taught or suggestion by the prior art. . . .

'289 Patent Prosecution History, March 7, 2016 (Ex. 6) at pp. 5-6 (emphasis and colored circles added, figure rotated for ease of reference). In other words, the Applicants argued the importance of the function of the claimed arrangement—a function that only Defendants' construction captures.

In the Notice of Allowance, the Examiner explained "[t]he examiner ***is persuaded*** that rocking by the canister about its central axis ***in the direction of the actuation member*** could risk triggering false counting, and that a ***canister support formation directly in line with the actuation member*** and the central canister axis ***could prevent rocking in this direction*** and thus reduce false counts." *See* '289 Patent Prosecution History, May 20, 2016, Notice of Allowance (Ex. 7) at 3 (emphases added).

To accomplish the stated purpose—preventing rocking in the direction of the actuation member—the canister support formation must be located directly adjacent to the actuation member. If this language is omitted from the construction, ***any*** support formation that aligned with the actuation member and central outlet port could satisfy this limitation. For example, in Figure 7D, support formation 146 (circled in purple), the central outlet port (circled in green), and the actuation member (circled in red) are aligned, but the support formation is not directly adjacent to the actuation member. In this arrangement, despite being aligned, support formation 146 (circled in purple) does nothing to prevent rocking ***in the direction of the actuation member*** (circled in red), allowing for changes in the height of the actuation member and miscounting (orange arrow).

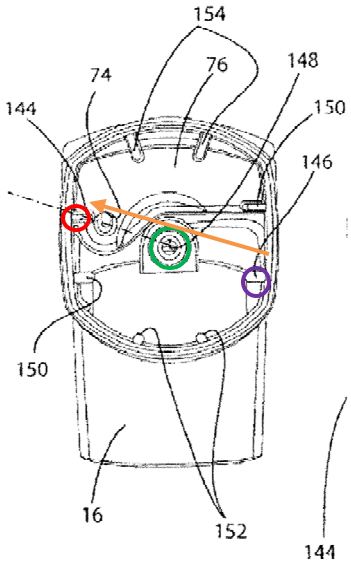


FIG. 7D

See '289 Patent (Ex. 1) at Fig. 7D (colored circles and line added, figure rotated for ease of reference). Defendants' proposed construction accounts for this required function. Plaintiffs' construction improperly attempts to capture subject matter that fails to meet the very aspect of the claim that it successfully argued was novel (i.e., arrangements that do not prevent rocking in the direction of the actuation member).

The patent specification is consistent with the Applicants' arguments for patentability. The specification requires that the canister support formation has a particular location relative to the actuation member—directly adjacent to it. *See* '289 Patent (Ex. 1) at 6:42-43 ("and a first inner wall canister support formation located directly adjacent the actuation member"); *see also id*. at 15:33-36 ("the inner wall **50** of the main body **10** is provided with a two-step support rail **144** which extends longitudinally along inside the main body and is ***located directly adjacent to the aperture 74***"). There is no other location disclosed in the patents that could possibly satisfy the

described purpose of the claimed configuration: "prevent[ing] the canister from rocking towards the position of the dose counter actuation member, thereby minimizing errors in counting." *Id*. at 6:57-58; *see also id*. at 6:44-49, 15:50-52 ("prevents the canister wobbling and chang[ing] the height of the actuation pin **34** as to undesirably alter the accuracy of the dose counter **36**.").

Only Defendants' construction is true to the specification, prosecution history, and reasons for allowance. For these reasons, Defendants' construction should be adopted.

C. <u>"canister fire sequence" / "first reset position" / "canister fire configuration" / "count configuration"</u>

Term	Defendants' Proposal	Plaintiffs' Proposal
"canister fire sequence"	"process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the fire configuration, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel"	"a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament"
"first reset position"	"configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel"	"a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the fire configuration"
"canister fire configuration"	"configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected"	"a configuration of the dose counter in which the medicament canister fires medicament"
"count configuration"	"configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose"	"a configuration of the dose counter whereby the dosage indicator has indicated a count"

1. "Canister Fire Sequence"

It is undisputed that the "canister fire sequence" refers to a series of configurations or positions that occur during "the process of ejecting medicament from an inhaler" (e.g., "before, while, and after the medicament canister fires medicament"). Rather, the dispute is whether the sequence of configurations must occur in a particular order, as recited by Defendants, or in any order, as recited by Plaintiffs. *See Automed Techs., Inc. v. Knapp Logistics & Automation, Inc.*, 236 Fed. Appx. 604, 605-606 (Fed. Cir. 2007) (construing claims to require particular order in view of the context of the specification and prosecution history).

The patent describes the order as the "start configuration" followed by the "first reset position" followed by the "canister fire configuration" followed by the "count configuration." *See* '289 Patent (Ex. 1) at 14:9-15:12. Moreover, the Applicants' prosecution arguments highlighted the necessity of the canister fire sequence occurring in a particular order. The Applicants argued that the prior art Bowman reference did not disclose a first reset position, a canister fires configuration, which is after the first reset position, and a count configuration, which is after the canister fire configuration. *See* '156 Patent, Prosecution History, April 20, 2017 Office Action Response (Ex. 11) at 7. After the "count," the user releases pressure on the canister, necessarily resulting in a final "start configuration," allowing for the next "canister fire sequence" to begin. *See* '289 Patent at 14:9-15:12; 5:39-46.

In addition to requiring the configurations to occur in a particular order, the patent also consistently, and without exception, requires the configurations to be particularly located. *See* '289 Patent (Ex. 1) at 14:9-15:12, 17:47-61, Figs. 10A-10E; *see also id*. at 5:56-58; 15:6-9. As explained below, the patent specification describes these "configurations" exclusively in relation to each other and the datum plane.

2. "Start Configuration"[2]

The patent, like Defendants' proposed construction, recites that the actuator pawl begins in a start position, in which the actuator pawl is above the datum plane and not yet engaged with a tooth of the ratchet wheel. *See* '289 Patent (Ex. 1) at 14:9-39 ("the lower side edge **98** of the actuator pawls is . . . 1.33 mm above [the] datum plain **220**") and ("if wheel **94** would try to rotate clockwise (backwards) . . . the back surface **140** of a tooth will engage and be blocked by the [actuator] pawl **80**.") and ("In this "start position,' the count pawl **138** engages on a non-return back surface **140** of one of the teeth **92** of the ratchet wheel **94**."); *see also id.* at Figs. 10A and 10B (showing the "start" configuration with the actuator pawl at 80 disengaged from the teeth of the ratchet wheel and the count pawl at 138 engaged with the teeth of the ratchet wheel); *id.* at 17:47-61 (describing average location of "start configuration" in relation to the datum plane).

3. "First Reset Position"

The next configuration is the "first reset position." The parties agree that in this configuration, the actuator pawl is "just engaged with one of a tooth of the ratchet wheel" (e.g., "position . . . in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel"). Plaintiffs' construction, however, allows this "configuration" to be anywhere, locationally, as long as it occurs before the fire configuration. The patent, however, makes clear that this configuration has a specific location with respect to the datum plane, and the other configurations in the claimed "canister fire sequence." The patent explains that the "first reset" configuration is a position where "the actuator pawl **80** has been depressed . . . to a position in

[2] Although not a separately proposed term, Defendants construe this term in the context of the "canister fire sequence" because it is necessarily the beginning and final configurations, and, as such, is a locational reference point for the separately recited configurations. *See* '289 Patent at 14:9-15:12, Figs. 10A-10E.

which [it] . . . is just engaged with one of the teeth **92 . . . .**" '289 Patent (Ex. 1) at 14:40-44; *See also id*. at Fig. 10C. The patent further explains that "[i]n this configuration, the . . . actuator [pawl] **80** is 0.64 mm above the datum plane **220**." *Id*. at 14:45-47; *see also id.* at 17:47-61 (describing average location of "first reset configuration" in relation to the datum plane). In other words, as properly set forth in Defendants' construction, it is "above the datum plane, but closer to the datum plane than in the start configuration."

4. "Canister Fire Configuration"

The next configuration is the "canister fire configuration." The parties agree that in this configuration, the medicament canister fires (e.g., the medicament is ejected). Plaintiffs' construction, again, allows this "configuration" to be anywhere, locationally. Similar to the "first reset configuration," the patent makes clear that this configuration has a specific location with respect to the datum plane and the other configurations in the claimed "canister fire sequence." The patent explains that, "Fig. 10D shows a configuration in which the actuator pawl **80** has been moved to a position lower than that shown in Fig. 10C and in which the metered dose valve . . . has at this very position fired in order to eject active drug and propellant." '289 Patent (Ex. 1) at 14:48-53; *see also id*. at Fig. 10D. The patent further explains that, "in this configuration . . . the actuator [pawl] **80** is 0.47 mm below the datum plane **220**." *Id*. at 14:57-59; *see also id.* at 4:57-65, 17:47-61 (describing average location of "canister fire configuration" in relation to the datum plane). In other words, as properly set forth in Defendants' construction, it is "lower than in the first reset position and below the datum pane."

5. "Count Configuration"

The next configuration is the "count configuration." The parties agree that in this configuration, "the dose counter has counted one dose" (e.g., "the dosage indicator has indicated

a count"). Again, the parties dispute whether this configuration must occur in a specific location, or anywhere. The patent, however, makes clear that the "count configuration" must occur in a specific location in relation to the datum plane and the other configurations in the sequence. The patent explains that "Fig. 10E shows a further step in the sequence, called a 'Count' position." '289 Patent (Ex. 1) at 14:60-61. "In this configuration, . . . the actuator [pawl] is 0.95 mm below the datum plane 220" and is "lower than in the fire configuration." *Id*. at 15:3-6; *see also id.* at 17:47-61 (describing average location of "start configuration" in relation to the datum plane). In other words, as properly set forth in Defendants' construction, it is "further below the datum plane than when in the canister fire position."

Following the count, the user releases pressure on the medicament canister and the final configuration is the "start configuration," where the inhaler is ready for the next use (or "canister fire sequence"). *See id.* at 14:9-10 ("Figs. 10A and 10B show the actuator pawl **80** . . . in a start position in which . . . [it] has not been pushed down during canister depression."); *see also id*. at Figs. 10A and 10B.

These terms should be construed in the context of the specification, which only extends to configurations having specific locations relative to each other and the datum plane. *See Honeywell Int'l, Inc. v. ITT Indus., Inc.,* 452 F.3d 1312, 1318 (Fed. Cir. 2006) (affirming construction of "fuel injection system component" as covering only "fuel filters," not other fuel injection system components, where specification only described fuel filters); *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.,* 467 F.3d 1370, 1376-78 (Fed. Cir. 2006) (context of specification indicates that term "derivatives" does not extend to structural analogs); *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.,* 450 F.3d 1350, 1354-56 (Fed. Cir. 2006) (context of specification indicates that term "host interface" only extends to a "direct parallel bus interface," and not serial interfaces).

Here, where the patent "consistently, and without exception" describes the configurations in relation to each other and the datum plane, Plaintiffs cannot use claim construction to expand their claims to encompass other relative locations. Accordingly, Defendants' constructions, which are consistent with the disclosures in the specification and the arguments in the prosecution history, should be adopted.

D. "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister"

Term	Defendants' Proposal	Plaintiffs' Proposal
"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister"	"plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet"	"a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister"

The dispute for this phrase centers on the construction of "a shoulder of a valve stem block."[3] Defendants' construction defines the shoulder consistently with the sole description in the patent. Plaintiffs' construction, to the contrary, does not provide any clarity as to what "a shoulder" is or how to identify a plane that passes through it. Clarity as to how to identify a plane passing through a shoulder is necessary to determine whether "in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder." Notably, Plaintiffs failed to identify this plane in their infringement contentions, and continue to ignore it in their proposed claim construction.

[3] Defendants use the phrase "plane or line" to encompass 2-D drawings as seen in the patent, where the "plane" appears as a "line." However, Defendants agree to drop "or line" from their construction for clarity, as it is not intended to limit or expand the scope of the claim.

The patent specification uses the term "shoulder" only one time, describing the "datum plane **220** which passes though [a] bottom surface or shoulder **41** of valve stem block **40**" and describes Figure 9 as showing this datum plane. '289 Patent (Ex. 1) at 14:18-19. Figure 9 shows the "bottom surface or shoulder" circled in red:

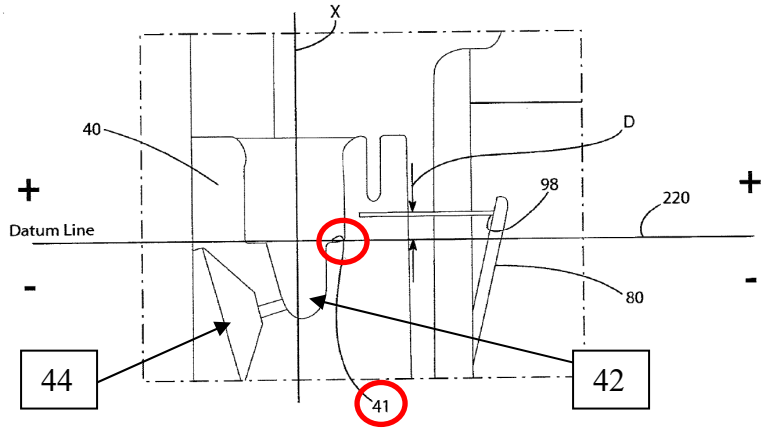


FIG. 9

'289 Patent (Ex. 1) at Fig. 9 (red circles, arrows, and text boxes added). In addition, Figure 3A, identifies the surrounding structures as "a nozzle for directing the canister contents towards an air outlet" at 44 and a "passageway to a nozzle" at 42. *See* '289 Patent (Ex. 1) at Fig. 3A, 12:26-29 ("The valve stem block **40** has a passageway **42** leading to a nozzle **44** for directing the contents of the canister **20** . . ."). As can be seen in Fig. 9 (annotated above), the "bottom surface or shoulder" is the area "where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet."

Plaintiffs' proposed construction does not define "shoulder" in a way that would allow a POSA to identify, with reasonable certainty, the datum plane in any valve stem block other than that claimed in the patent. Defendants' construction, to the contrary, clearly describes how to identify the "shoulder" or "bottom surface" of the valve stem block, consistent with the only

guidance in the specification. For at least these reasons, the Court should adopt Defendants' proposed construction.

E. "counter display arranged to indicate dosage information"

Term	Defendants' Proposal	Plaintiffs' Proposal
"counter display arranged to indicate dosage information"	"structure displaying the number of doses remaining"	"a component of the dose counter that displays information regarding the number of doses remaining"

The sole independent claim of the '808 Patent requires that the claimed dose counter have a "counter display arranged to indicate dosage information." Defendants propose a straightforward construction consistent with the purpose of a dose counter—informing a user how many doses remain in the inhaler. Plaintiffs, however, propose a nonsensical construction that ignores the realities of what a dose counter is intended to do and that would invalidate the claims if adopted.

First, Defendants' proposed construction properly requires the counter display to display "the number of doses remaining." The '808 Patent explains that, one of the drawbacks of prior art inhalers was "that it is difficult to determine how much active drug and/or propellant are left in the inhaler." '289 Patent (Ex. 1) at 1:49-51. This situation is "potentially hazardous for the user since dosing becomes unreliable and backup devices [are] not always available." *Id*. at 1:52-54. Recognizing this, Defendants' proposed construction correctly requires that the counter display actually displays "the number of doses remaining." This is consistent with every embodiment in the patent specification. *See id*. at 13:12-14 (the tape **112** has a series of regularly spaced numbers **114** displayed therealong to indicate ***a number of remaining doses*** in the canister **20**."); 17:8-10 ("the number **114** shown in FIG. 8D being '200,' thereby ***indicating that 200 doses are remaining*** to be dispensed from the canister **20**"); 19:14-17 (This is highly advantageous, since the tape **11** is prevented from moving to a position in which it will give an incorrect reading regarding ***the number of doses in the canister***.") (emphases added).

Plaintiffs' proposed construction, on the other hand, only requires the display of "information regarding the number of doses remaining." During the Parties' various meet and confers, Plaintiffs confirmed that this meant a component displaying only one unit (e.g., only the hundreds digit, only the tens digit, or only the ones digit) would still be a "counter display." This construction is non-sensical. A display that does not allow a patient to distinguish between 5, 15, 50, or 500 doses remaining, because it only displays a "5," fails to provide the necessary dosage information for a patient to determine how many doses are left in the inhaler.

Second, Defendants' proposed construction properly identifies the "counter display" as "a structure." The patent specification only discloses a "counter display" that is a single structure. *See, e.g.*, '289 Patent (Ex. 1) at 13:12-14, 17:8-10, 19:14-17, and Figs. 6A, 6C, 6E, 8C, 23, and 24. As can be seen, the "counter display" is a single structure, displaying the entire number of doses remaining (e.g. 200, 198):

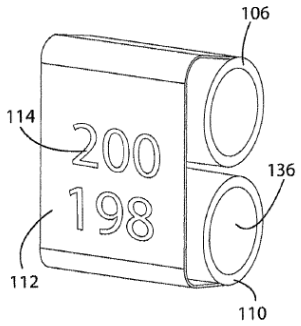


FIG. 6E

Id. at Fig. 6E.

Plaintiffs' proposed construction, however, allows the "counter display" to be comprised of multiple displays or "components," which may move independently of each other. *See* Plaintiffs' June 18, 2021 Letter (Ex. 12) at 4 ("Teva confirms that it does not believe ***a single component*** of the dose counter that moves in 'multiple directions at a time' moves in a 'first direction.'") and '808 Patent claim 1 ("arranged to move the counter display in a first direction").

For example, under Plaintiffs' proposed construction, a device having two separate displays, one displaying tens and one displaying units (as shown by the red line below), and each moving independently of the other would be encompassed by the claims.

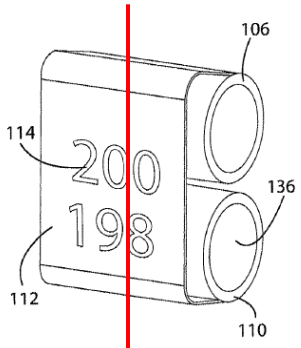


FIG. 6E

'289 Patent (Ex. 1) at Fig. 6E (red line added). However, such a construction lacks written description support and is not enabled. The patent specification includes no disclosures of multiple displays. Nor does it include any guidance as to how such a system would work in the context of the invention – the patent specification only discloses how to move a single counter display in a single direction at a time. *See*, *generally* '289 Patent (Ex. 1). A POSA would be required to determine how to move a second display (units), simultaneously with the first display (tens) (e.g., to change the displayed doses in the above image from 200 to 198), or independently (e.g., to change the displayed doses in the above image from 198 to 196 by moving only the units display), with no guidance from the specification. Plaintiffs' construction is also broad enough to include "counter displays" where each display may move in different directions at the same time. The patent specification is silent as to how such actions could be accomplished. "When claims are amendable to more than one construction, they should when reasonably possible be interpreted to preserve their validity." *Modine Mfg. Co. v. USITC*, 75 F.3d 1545, 1557 (Fed. Cir. 1996), abrogated on other grounds by *Festo Corp v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d

558 (Fed. Cir. 2000). Plaintiffs' construction does precisely the opposite. Accordingly, the Court should adopt Defendants' proposed construction.

F. "first station" / "second station"

Term	Defendants' Proposal	Plaintiffs' Proposal
"first station"	"first structure on which the counter display is located"	"a first region"
"second station"	"second structure, separate from the first structure, on which the counter display is located"	"a second region"

The terms "first station" and "second station" have clear meanings in view of the specification and the claims—Defendants' constructions are consistent with these meanings. Plaintiffs' constructions are non-sensical and raise more questions than they answer.

The sole independent claim of the '808 Patent recites that the counter display moves "***from a*** first station ***to a*** second station." '808 Patent (Ex. 4) at claim 1 (emphasis added). In addition, the specification explains that movement of the counter display is regulated "***at the*** first station." '289 Patent (Ex. 1) at 2:2:45-50. The specification continues by explaining that, "[t]he first station may compromise a first shaft, the tape being arranged on the first shaft and to unwind therefore upon movement of the counter display." *Id*. at 2:65-67. Notably, throughout the remaining 19 columns of the specification, the only "station" from which counter display moves is a first structure (*e.g.,* shaft, stock bobbin, or bobbin). *See e.g.*, *id*. at Abstract ("the tape unwinding ***from a stock bobbin*** during use of the inhaler"), 2:4-5 ("[a] ***stock bobbin*** of the counter, ***from which*** the tape is unwound"), 4:38-39 ("the tape unwinding ***from a stock bobbin***"), 4:39-44 ("a rotation regulator being provided for the ***stock bobbin*** . . . permitting incremental unwinding"), 5:36-37 ("the tape being positioned on a ***tape stock bobbin*** and being arranged ***to unwind therefrom***), 8:55-58 ("the dose counter having a display tape arranged to be incrementally driven ***from a tape stock bobbin*** onto an incremental tape take-up drive"), 9:60-61 ("[t]he main elongate tape structure may

have at least one end thereof would on a ***bobbin or shaft***"), 13:17-18 ("the tape **112** is incrementally and gradually wound ***onto the tape reel shaft* 106 *from the second shaft***"), 16:28-29 ("[t]he tape **112** is attached at one end (not shown) to the tape stock bobbin **110** and is ***wound onto the bobbin***"), 19:28-30 ("a force of 0.3 to 0.4 N needs to be applied to the tape **112** to overcome the regulator at the stock bobbin **110**") (emphases added).

The specification also demonstrates that the first and second stations must be separate structures. *See id*. at 3:51-52 ("The ***second shaft*** may be . . . ***spaced from and parallel to*** the ***first shaft***."); 13:3-8 ("The dose counter . . . includes a chassis **102** having a ***first shaft* 104** . . . and a ***second shaft*** . . . which is ***parallel to and spaced from*** the first shaft"); 2:62-64 ("The first station . . . is located before a display location"); 16:47-48 ("second shaft **104**, be in a position to be located in the window") (emphases added).

Defendants' construction correctly reflects that the "first station" is a structure on which the counter display is located, and that the "second station" is a separate structure to which the counter display moves.

Plaintiffs appear to have adopted their construction from an excerpt of the summary of the invention stating, "[t]he first station may comprise ***a region*** of the dose counter where tape is held . . . ." '289 Patent (Ex. 1) at 2:62-63 (emphasis added). However, their construction improperly shortens the phrase to cut off "where the tape is held." By cutting off the remainder of the phrase, Plaintiffs completely change the meaning of the term, broadening it to encompass nearly everything and every location. Plaintiffs' proposed construction begs the question, "region of what?" Plaintiffs' construction is a blatant attempt to use claim construction to expand its claims to cover, for example, dose counters using two gears rotating in place, to display the number of doses remaining. But the claims require "a counter display" "to ***move*** . . . in a first direction ***from***

a first station ***to a*** second station." (i.e., from one structure to another structure). The Court should reject Plaintiffs' attempt to expand the scope of their claims and adopt Defendants' proposed constructions.

G. "separate counter chamber" / "dose counter chamber"

Term	Defendants' Proposal	Plaintiffs' Proposal
"separate counter chamber"	"discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located"	"a separate chamber of the inhaler in which the dose counter is located"
"dose counter chamber"	"space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located"	"a separate chamber of the inhaler in which the dose counter is located"

These two claim phrases are grouped together because the dispute for both centers on the term "chamber."

Plaintiffs' proposal includes the term "chamber" in the proposed definition which does nothing to resolve the parties' infringement and invalidity disputes. Defendants' proposed construction provides the structural description required by the words of the claims themselves. Specifically, claim 2 specifies that "a dose counter chamber" is "formed in the body." This wording indicates that the "chamber" is not simply an area or open space in where the dose counter is positioned. Rather, the phrase "formed in the body" indicates that the dose counter "chamber" must have some structural definition in the body. In addition, claim 3 recites a cover that conceals the dose counter chamber indicating the dose counter chamber is defined space within the body. *See* '512 Patent (Ex. 5) at claim 3 ("a cover . . . to conceal the dose counter chamber").

Neither the term "chamber," generally, nor the phrase "dose counter chamber," specifically, is explicitly defined in the specification. However, the specification makes clear there are two separate chambers within the inhaler main body, explaining:

> The inhaler main body may include a canister receiving portion and a separate counter chamber, the dose counter being located within the main body thereof, the incremental output member and actuator thereof inside the counter chamber, ***the main body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber***, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.

'289 Patent (Ex. 1) at 6:24-37 (emphasis added).

The specification states in no uncertain terms that the dose counter chamber is "separate" from the canister receiving portion and that wall surfaces separate these chambers. *Id.* at 7:20-29 ("a counter chamber separate from the canister housing" and "a wall which separates the counter chamber and the canister housing"); 8:33-37 ("a dose counter chamber of the body which is separated from the main part of the body"). In addition, Figure 8A depicts this separate dose counter chamber (at 66) defined by the inner walls (blue and green):

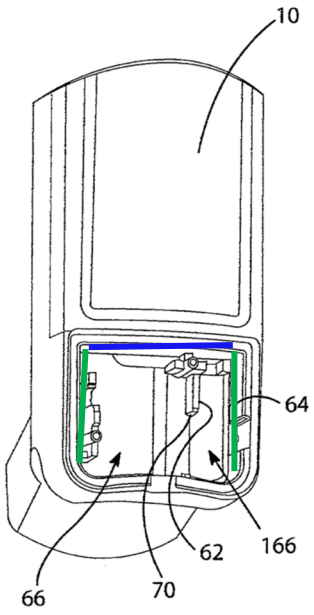
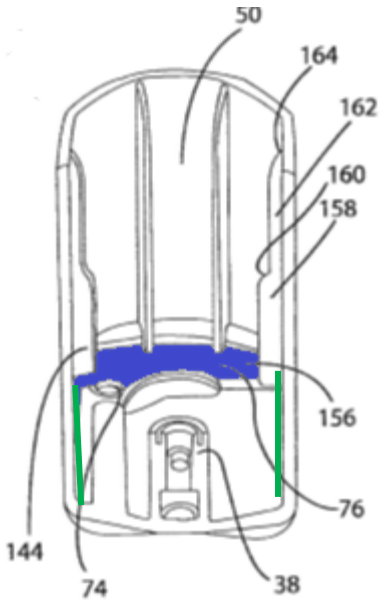


FIG. 8A

The specification further explains that the dose counter chamber is separated from the canister chamber by a separator wall: "a separator wall **76** which separates the canister chamber **18** from the dose counter chamber **66**." '289 Patent (Ex. 1) at 12:49-52. The separator wall 76 is depicted in Fig. 7C (in blue). As can be seen, this "separator wall" is the inner wall through which a portion of the actuation member extends (**74**). *See id*. at 12:49-52.



As is evident from the description and the figures, the dose counter chamber is defined by the inner walls of the main body (green) and the inner wall separating the dose counter chamber from the canister chamber (blue). Defendants' proposed constructions describe the structural requirements of the chamber and its relation to the other components of the inhaler. Plaintiffs' construction simply rearranges the terms of the phrase, which does not help resolve the question of what the "chamber" is and how to identify it. Accordingly, the Court should adopt Defendant's proposed construction.

H. "the body"

Term	Defendant's Proposal	Plaintiffs' Proposal
"the body"	Indefinite	"inhaler body" - '156 Patent, 22:64, 67 "dose counter body" - '156 Patent, 22:66

The claim term "body" appears in dependent claim 12 in the '156 Patent. Claim 12 is dependent on claim 11, which is dependent on claim 1. Claims 11 and 12, and the preamble of claim 1 read as follows (emphasis added on "the body" at issue):

> 12. An inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber; **the body,** ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.
>
> 11. An inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1.
>
> 1. A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

Reading claims 1 and 11 together, there is only one element that is "the body:" the inhaler body. In fact, the parties have agreed that, in claim 1 of the '156 Patent "body" means "the body of the inhaler." Dkt. No. 102 at 4. The preamble of claim 1 describes the body of the inhaler in which the claimed dose counter is intended to fit. Claim 1 refers to no other "body."

This interpretation is confirmed by claim 11, which is directed to "an inhaler" that comprises "the body" in claim 1 (as well as the dose counter from claim 1), and the preamble of claim 12, which recites "an inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber. Accordingly, in claim 12 the only "the body"

for which there is antecedent basis is "the body of the inhaler" originally recited in the preamble of claim 1.

Claim 12 recites "the body, ratchet wheel and actuator being located inside the counter chamber." The claim as written is indefinite because the only body for which there is antecedent basis is "the body of the inhaler." In other words, the claim recites: "An inhaler as claimed in claim 11 in which [the body of the inhaler] includes a canister receiving portion and a separate counter chamber; [the body of the inhaler], ratchet wheel and actuator being located inside the counter chamber . . . ." The counter chamber cannot simultaneously include a separate counter chamber and be located inside the counter chamber. When read with the only antecedent basis available, the claim is non-sensical, impossible to understand, and insolubly indefinite.

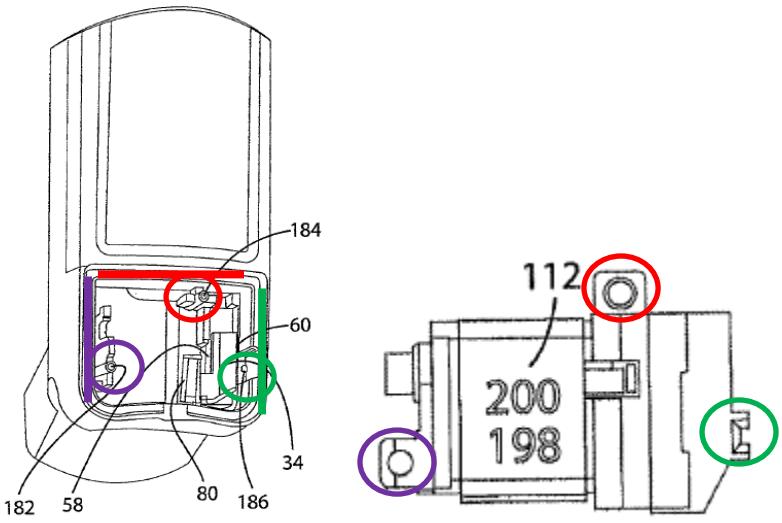
Even if one concludes that the second "the body" in claim 12 merely lacks antecedent basis, the indefiniteness issue is not resolved by the specification or the claims. The specification describes a number of different "body" terms including "main body of the dose counter" ('289 Patent (Ex. 1) at 3:13; 3:51-52; 10:50-51), "main body of the incremental count system" (*id*. at 4:51-52; 6:8); "main body of the inhaler" (*id*. at 6:46; 10:43; 11:11-12; 11:18; 11:30; 12:31; 14:23; 16:6-7; 17:14-15); "body for retaining a medicament store" (*id*. at 7:28; 7:63); "the main canister body" (*id*. at 9:19-21); "inhaler main body" (*id*. at 6:24; 10:36-37; 11:19; 11:24-25; 11:33-34; 12:31); and "actuator body" (*id*. at 1:33-34). As one skilled in the art cannot determine to which "body" the claim is referring; it is therefore indefinite.

I. "different sides"

Term	Defendant's Proposal	Plaintiffs' Proposal
"different sides"	"distinct surfaces where each pin/aperture of the chassis connects to a different face of the body"	"not the same side"

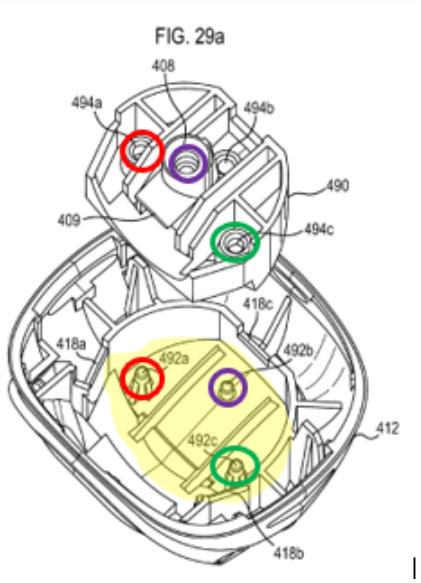
The sole independent claim of the '512 Patent requires that the pins or apertures on the chassis of the dose counter, are "positioned on ***different sides*** of the chassis for stabilizing the chassis on the body." '512 Patent (Ex. 5) at claim 1 (emphasis added). Consistent with arguments the Applicants made to distinguish the prior art, Defendants' proposed construction requires that the pin/aperture connections each occur on a different surface. Plaintiffs' construction improperly allows the pin/aperture connections to all be on the same surface, as long as they are on different sides of that surface.

The specification makes clear that "different sides" requires that the pin/aperture connections are on different surfaces. For example, Figures 8B and 6C, show pins attaching to their respective apertures on different surfaces of the inhaler body (shown in red, purple, and green lines):



'289 Patent (Ex. 1) at Figs. 8B, 6B (colored notations added). During prosecution, the Applicants relied on the location of these pin and aperture connections to distinguish the prior art.

As seen in the images below, in prior art U.S. Patent Application No. 2012/0006322 ("Anderson"), the pins and apertures are connected on the same surface (shown in yellow) of the body.



See Anderson (Ex. 13) at Fig. 29a (highlighting added).

When prosecuting the parent applications of the '512 Patent,[4] the Applicants distinguished Anderson, arguing:

> Sole independent claim 1 now recites that 'wherein either the plurality of pins or the plurality of mating apertures are positioned on three different sides of the chassis.' The Applicant submits that such a feature is advantageous for firmly mounting the dose counter into the inhaler body. ***In contrast to this feature of claim 1, Anderson's pins 492a-c and apertures 494 a-c (see above) are each positioned on the same side of their respective parts***.

U.S. Patent 9,533,111, Prosecution History, Sept. 28, 2016 Office Action Response (Ex. 10) at 4 (emphasis added). As can be seen in the above images, to distinguish Anderson, "different sides" must be interpreted to require each pin/aperture pairing to be on different ***surfaces*** such that each pin/aperture of the chassis connects to a different face of the body.

[4] In allowing the claims of the '512 Patent, the Examiner explained: "Further reasons for the allowability of this subject matter can be seen in the prosecution history of parent applications 15/289,553 and 14/713,643, which became patents 9,737,674 and 9,533,111." '512 Patent Prosecution History, Feb. 24, 2020 Notice of Allowance (Ex. 14).

Defendants' proposed construction, like Applicants' arguments to the Patent Office, requires the apertures/pins to connect the chassis to the body on different surfaces. In contrast, Plaintiffs' construction encompasses connections to the same face of the body, exactly the scope that was relinquished to distinguish Anderson. For at least these reasons, Defendants' proposed constructions should be adopted.

J. "formed in the body"

Term	Defendant's Proposal	Plaintiffs' Proposal
"formed in the body"	"an integrated part of the body"	"located in the body"

The main dispute between the parties is whether the structure that forms the dose counter chamber in the body is a part of the body (i.e., integrated), or not necessarily part of the body (i.e. located in the body, but removable). The specification and figures make plain that the dose counter chamber is formed by walls of the body (*see supra* Section II.F).

The words of the claim signal that the term "formed" must mean something other than location because the location is specifically recited at the end of the claim: "a location beneath the medicament canister." As discussed above with respect to claim 2 of the '512 Patent, the "dose counter chamber" is defined by the inner walls of the main body and the inner wall separating the dose counter chamber from the canister chamber, i.e. the separator wall **76**. The inner walls of the main body are obviously an "integrated" part of the body. Likewise, the separator wall is depicted in the figures as integrated with the inner walls of the main body. There is no indication in the intrinsic evidence that the walls that make up the dose counter chamber are non-integrated or free floating in the body. Plaintiffs' proposal essentially reads out the term "formed," allowing the dose counter chamber to be any structure found inside the body of the inhaler, including a removable chamber. Nothing in the specification, claims, or prosecution history supports such a

broad interpretation of "formed in the body." Accordingly, the Court should adopt Defendants' proposed construction.

K. "positioned at opposite ends of the inside surface of the main body to face each other"

Term	Defendant's Proposal	Plaintiffs' Proposal
"positioned at opposite ends of the inside surface of the main body to face each other"	"positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail"	"located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other"

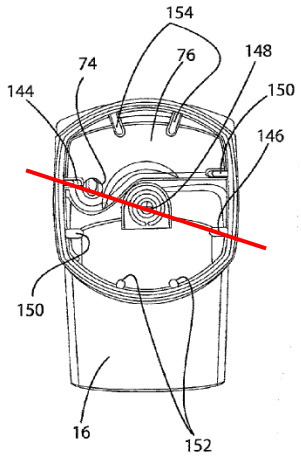
The crux of the parties' dispute is what "opposite ends" means in the context of the recited phrase. "Opposite ends" has a definite structural meaning and that meaning must be defined in relationship to the "longitudinal axis X."

The term "opposite ends" limits the positioning of the support rails in the claims. *See* '289 Patent (Ex. 1) at claim 6; '587 Patent (Ex. 2) at claims 6, 7 (directly, or through dependency, reciting, "a plurality of support rails each of which extends longitudinally along the inside surface of the main body."). Claim 7 further specifies that the rails are "at opposite ends . . . to face each other." *Id*. at claim 7. A clear explanation of rails that are positioned "at opposite ends" and "face each other" is provided by the specification:

> As shown in FIGS. 7C and 7D, the inner wall **50** of the main body **10** is provided with a two-step support rail **144** which extends longitudinally along inside the main body and is located directly adjacent the aperture **74**. As shown in FIG. 7B a ***diametrically opposed*** two-step support rail **146** is also provided and this ***diametrically opposed*** in the sense that a vertical plane (not shown) can pass substantially directly through the first rail **144**, the aperture **74**, a central aperture **148** of the valve stem block **40** (in which canister stem **25** is located) and the second two-step support rail **146**.

'289 Patent (Ex. 1) at 15:33-43 (underline and bold italic emphases added). In Fig. 7D, which is a top view of the main body, support rail 144 is identified as diametrically opposed to support rail

146, such that a straight line can be drawn from support rail 144 to support rail 146 through the center of the longitudinal axis X, as shown by the red line depicting the unshown vertical plane described in the specification.



Id. at Fig. 7D (redline added). As discussed above, the Applicants emphasized the criticality of the particular arrangement of the support rails, the longitudinal axis X, and the actuation member to prevent rocking. *See supra* Sections II.A and II.B. Plaintiffs' proposal fails to resolve what "opposite ends" means in the context of the main body (which may be irregularly shaped).

Accordingly, for rails to be positioned at "opposite ends," the rails must be such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail as shown in amended Fig. 7D. Accordingly, the Court should adopt Defendants' proposed construction.

L. <u>"step formed thereon"</u>

Term	Defendant's Proposal	Plaintiffs' Proposal
"step formed thereon"	"A stepwise increase in the extent to which the support rail extends inwardly"	"a location of changing width dimension thereon"

The dispute between the parties centers on how to define the term "step(s)" in the phrase "step[(s)] formed thereon." Defendants' proposal is consistent with both the plain meaning of the word "step," and the description of a "step" in the specification:

> It will be clear from FIG. 7C for example that the two-step rails have a . . . first portion having a substantially constant radial or inwardly-extending width, a first step **160** leading to a second portion **162** of the rail, the second portion **102** having a lesser radial or inwardly extending extent than the first portion **156** . . . .

'289 Patent (Ex. 1) at 15:62-16:3. The specification describes the rails in terms of the extent that the rail extends inwardly (width) at a particular portion of the rail. For the rail to have a step, the rail must have a portion that extends inwardly to one extent, and another portion that extends inwardly to a different extent from the first portion. By definition, in order to go from one portion to the other there must be an increase to the extent the rail is inwardly extending. The position where the increase occurs is a step. The steps are best illustrated in Fig. 7C:

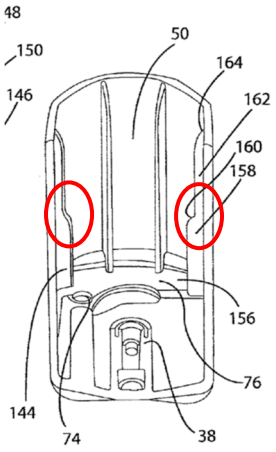


FIG. 7C

See '289 Patent (Ex. 1) at Fig. 7C (red circles added). As can be seen, numeral **162** is one portion having a substantially-constant inwardly-extending width and **158** is a second portion with an increased substantially-constant inwardly-extending width. *Id.* at 15:62-16:3. Numeral **160** is where the increase occurs, i.e. a step. *Id.* Defendants' proposed construction articulates this

structure. Plaintiffs' proposal, to the contrary, encompasses a gradual incline or slanted rail, and therefore is inconsistent with the plain and ordinary meaning of the term "step." Accordingly, the Court should adopt Defendants' proposed construction.

M. "aperture"

Term	Defendant's Proposal	Plaintiffs' Proposal
"aperture"	"hole"	"an opening or open space: hole"

Without explicitly defining "aperture" as a hole, the claim terms themselves and the specification consistently describe it and illustrate it as such. The claims each describe the aperture as something formed in a wall "through which . . . the actuation member extends." Similarly, the specification generally, and with respect to the inner wall specifically, consistently describes the "aperture" as going "through" something, e.g., a wall. *See e.g.*, '289 Patent (Ex. 1) at 6:24-33; 7:20-25; 12:47-50; 15:33-42; 16:4-13; Figs. 6B, 7A-7D. Likewise, the figures (for example Figure 7B) show the aperture **74** to be a hole which goes through the wall in which it is formed.

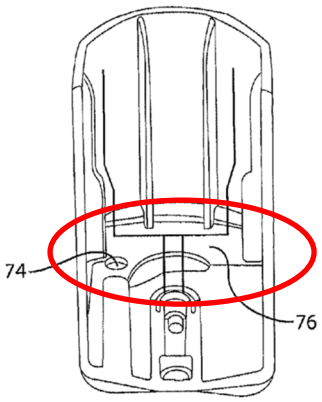


FIG. 7B

Defendants' proposed construction is consistent with the plain meaning of aperture, and the descriptions in the specification. Plaintiffs' proposed construction is so vague as to create more issues than it resolves. The phrase "open space," seemingly does not even encompass an aperture that must be formed through the wall. This is inconsistent with the plain language of the claim

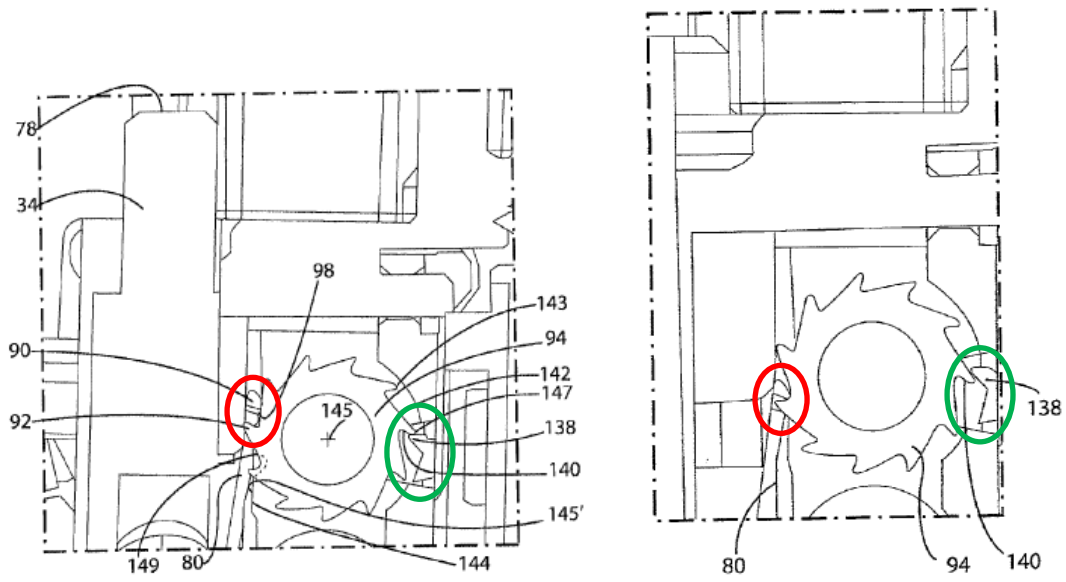
and should be rejected for this reason alone. Further, there is nothing in the specification or file histories that would even suggest that the aperture is something other than a hole. For these reasons, Defendants proposed construction should be adopted.

N. "count pawl"

Term	Defendant's Proposal	Plaintiffs' Proposal
"count pawl"	"a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel"	"a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the rachet wheel"

The primary disputes between the parties are whether the construction must structurally differentiate "the count pawl" from the actuator pawl, and whether the count pawl need only be "capable of" engaging with a second tooth of the rachet wheel.

The specification makes plain both that the "count pawl" is a separate structure from the actuator pawl, and that the "count pawl" engages teeth independently of the actuator pawl. For example, as shown below, in Figure 10B (left), the actuator pawl (80) is not yet engaged with the ratchet wheel, while the "count pawl" (138) "engages on a non-return back surface **140** of one of the teeth **92** of the ratchet wheel." *See* ' 289 Patent (Ex. 1) at 14:14-47; Fig. 10B. In Figure 10D (right), both the count pawl and actuator pawl are separately engaging different teeth of the ratchet wheel 94 simultaneously. *See also id*. at 11:39-41; 13:42-54; 14:11-15; 14:16-26; 14:5-15:14; 15:15-33; '156 Patent Prosecution History, September 9, 2016 Office Action Response (Ex. 15) at 6-8 ("the actuator pawl 80 pulls down on one of the teeth 140 of the ratchet wheel … The dose counter also includes a separate count pawl 138. The actuator pawl 80 and count pawl 138 are engaged with different teeth 140 as shown in Figure 10E.").



See '289 Patent (Ex. 1) at Figs. 10B and 10D (colored notations added)

This is consistent with the words of the claim, which recite that the actuator pawl is a part of the actuator, and the count pawl is a part of the dose counter. The specification and figures do not contemplate a structural arrangement different from the Defendants' proposed construction. *See id*. at 13:41-43 ("[T]he chassis **102** is provided with an anti-back drive tooth **138** or count pawl **138** which is resiliently and substantially fixedly mounted thereto. . . . the actuator pawl **80** pulls down on one of the teeth **92** of the ratchet wheel **94** and rotates the wheel **94** anticlockwise as shown in FIG. 6D so as to jump one tooth **92** past the count pawl **138**").

Plaintiffs' proposed construction allows the "count pawl" and actuator pawl to be part of the same structure, and even the same pawl, introducing ambiguity that is not supported by any intrinsic evidence. Accordingly, Defendants' proposed construction should be adopted.

IV. CONCLUSION

For the foregoing reasons, the Court should adopt Defendants' proposed construction and reject Plaintiffs' proposals.

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